



COMMONWEALTH of VIRGINIA

DEPARTMENT OF ENVIRONMENTAL QUALITY

NORTHERN REGIONAL OFFICE

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VIRGINIA WASTE MANAGEMENT BOARD ENFORCEMENT ACTION - ORDER BY CONSENT ISSUED TO VIRGINIA HOSPITAL CENTER ARLINGTON HEALTH SYSTEM FOR VIRGINIA HOSPITAL CENTER PERMIT BY RULE NO.566

SECTION A: Purpose

This is a Consent Order issued under the authority of Va. Code § 10.1-1455, between the Virginia Waste Management Board and the Virginia Hospital Center Arlington Health System, regarding the Virginia Hospital Center, for the purpose of resolving violations of the Virginia Waste Management Act and the applicable regulations.

SECTION B: Definitions

Unless the context clearly indicates otherwise, the following words and terms have the meaning assigned to them below:

1. "Administrative Process Act" or "APA" means Chapter 40 (§ 2.2-4000 *et seq.*) of Title 2.2 of the Va. Code.
2. "Aramark" means Aramark Healthcare Support Services, LLC, a limited liability company authorized to do business in Virginia and its members, affiliates, partners, subsidiaries, and parents. Aramark is a "person" within the meaning of Va. Code § 10.1-1400.
3. "Board" means the Virginia Waste Management Board, a permanent citizens' board of the Commonwealth of Virginia, as described in Va. Code §§ 10.1-1184 and -1401.
4. "Department" or "DEQ" means the Department of Environmental Quality, an agency of the Commonwealth of Virginia, as described in Va. Code § 10.1-1183.

5. "Director" means the Director of the Department of Environmental Quality, as described in Va. Code § 10.1-1185.
6. "Facility" means the Virginia Hospital Center, located at 1701 North George Mason Drive in Arlington, Virginia, which is owned and operated by the Virginia Hospital Center Arlington Health System.
7. "Notice of Violation" or "NOV" means a type of Notice of Alleged Violation under Va. Code § 10.1-1455.
8. "NRO" means the Northern Regional Office of DEQ, located in Woodbridge, Virginia.
9. "Order" means this document, also known as a "Consent Order" or "Order by Consent."
10. "Permit" means Permit by Rule (PBR) No. 566, which was issued by the Director to Virginia Hospital Center on November 4, 2013.
11. "Regulations" or "VSWMR" means the Virginia Solid Waste Management Regulations, 9 VAC 20-81-10 *et seq.*
12. "RMW" means regulated medical waste.
13. "STI Chem-clav Unit" means a continuous feed steam sterilization / destruction system for bio-hazardous waste including regulated medical waste, infectious waste and clinical waste.
14. "Va. Code" means the Code of Virginia (1950), as amended.
15. "VAC" means the Virginia Administrative Code.
16. "Virginia Hospital Center" or "VHC" means Virginia Hospital Center Arlington Health System, a corporation authorized to do business in Virginia and its affiliates, partners, and subsidiaries. Virginia Hospital Center Arlington Health System is a "person" within the meaning of Va. Code § 10.1-1400.
17. "Virginia Waste Management Act" means Chapter 14 (§ 10.1-1400 *et seq.*) of Title 10.1 of the Va. Code. Article 2 (Va. Code §§ 10.1-1408.1 through -1413.1) of the Virginia Waste Management Act addresses Solid Waste Management.
18. "VRMWR" means the Virginia Regulated Medical Waste Management Regulations, 9 VAC 20-120-10 *et seq.*
19. "VSWMR" or "Regulations " means the Virginia Solid Waste Management Regulations, 9 VAC 20-80-10 *et seq.*

SECTION C: Findings of Fact and Conclusions of Law

1. The Facility is a hospital center located in Arlington, Virginia that is owned by VHC. The Facility is the subject of the Permit which authorizes VHC to use alternative treatment technology in the form of a STI Chem-clav unit to treat its RMW. After proper treatment of the RMW through the STI Chem-clav unit, the RMW may be disposed of as solid waste in a solid waste management facility. The STI Chem-clav unit is operated by Aramark.
2. 9 VAC 20-120-50(A) states that the VRMWR "...applies to all persons who manage medical waste, own or operate regulated medical waste management facilities..."
3. On May 19, 2014 and December 8, 2014, Department staff inspected the Facility for compliance with the requirements of the Virginia Waste Management Act, the Regulations and the Permit. Based on the inspections and follow-up information provided by VHC, Department staff made the following observations:

- a. VHC failed to meet the requirements of Financial Assurance (FA). The revised FA measures were required no later than December 30, 2014. DEQ did not receive the documents until the enforcement meeting held on February 25, 2015. FA coverage had lapsed for the time period between December 30, 2014 and February 25, 2015.

9 VAC 20-70-111(E) requires that "[t]he owner or operator of each solid waste management unit shall establish financial assurance in current dollars for the cost of closure of the unit in compliance with 9 VAC 20-70-140. The owner or operator shall provide continuous coverage for closure until released from financial assurance requirements by the director."

- b. The facility was using Stericycle containers to store regulated medical waste (RMW) during outages of the Chem-clav unit. The Stericycle container was not locked and the staff indicated the container was delivered without a padlock. Access to the 50 cubic yard container was not secure, and a red bag was observed under one of the containers.

The Permit under the Infectious Waste Plan requires that if the STI Chem-Clav unit is not operational, the facility will implement the back-up system. The backup system plans on storing the untreated RMW in a Bulk Outer Packaging Container (BOP), which will be secured when unattended. RMW will be placed in the BOP to prevent leakage and be packed securely enough to ensure that rodents or vermin do not get into the RMW bags.

9 VAC 20-120-420 requires that all vehicles and equipment used in the transportation of regulated medical waste must have access control that limits

access to those persons specifically designated to manage regulated medical waste.

- c. The floor of the hallway being used for storage of RMW had cracks and seams that were not sealed and the concrete did not appear to have any coating to render it impermeable to liquids.

9 VAC 20-120-340 requires that “[a]ll areas used to store regulated medical waste must be clean and impermeable to liquids. Carpets and floor coverings with cracks or gaps shall not be used in storage area. Where tile floors are used and seams are present in the tile, the floor must be sealed with wax or other floor coatings in order to meet this requirement. Vectors shall be controlled.”

- d. While access to the hallway used for RMW storage has been restricted by the installation of an electronic magnetic lock, the back door was found to be unlocked upon arrival. When the inspector returned with facility management the door was propped open.

9 VAC 20-120-350 requires that “[a]ll areas used to store regulated medical waste must have access control that limits access to those persons specifically designated to manage regulated medical waste.”

- e. Containers used for RMW were not disinfected as required and no records were provided to prove on-site decontamination. This includes both the red rectangular bins and the grey rolling trash cans.

9 VAC 20-120-380 requires that “[w]aste managed in reusable carts or containers shall meet the special requirements for reusable containers in 9 VAC 20-120-260.”

9 VAC 20-120-260 states that “[r]egulated medical waste may be conveyed in reusable carts or containers under the following conditions: 1. The waste in the cart or container is packaged and labeled fully in accordance with 9 VAC 20-120-210 through 9 VAC 20-120-240. 2. Immediately following each time a reusable cart or container is emptied and prior to being reused it is thoroughly cleaned with detergent or general purpose disinfectant.”

- f. Operational logs indicating the date, time, operator, and quantity of RMW processed were not available for the Chem-clav during the site visit. The Staff at the facility were unable to download any data from the new Chem-clav and were unsure of the computer's data storage capacity.

9 VAC 20-120-640(1)(c) requires that all alternative treatment facilities for regulated medical waste shall maintain the following level of operational performance at all times: A log shall be kept at each alternative treatment unit that

is complete for the preceding three year period. The log shall record the date, time and operator; the type and approximate amount of solid waste treated; and the dates and results of calibration and testing. Where multiple alternative treatment units are used, a working log can be maintained at each unit and such logs periodically consolidated at a central location. The consolidated logs and all performance parameter recordings shall be retained for three years and be available for review.

- g. VHC reported via a phone call, within the required 24 hours, that the Chem-clav unit had failed the "A-test" on November 18, 2014. A written follow-up was submitted on December 8, 2014.

9 VAC 20-120-760(c)(3) requires that the Permittee "report to the department any noncompliance or unusual condition that may endanger health or environment. Any information shall be provided orally within 24 hours from the time the permittee becomes aware of the circumstances. A written submission shall also be provided within five calendar days of the time the permittee becomes aware of the circumstances. The written submission shall contain a description of the noncompliance and its cause; the period of noncompliance, including exact dates and times, and, if the noncompliance has not been corrected, the anticipated time it is expected to continue. It shall also contain steps taken or planned to reduce, eliminate and prevent reoccurrence of the noncompliance."

- 4. Based on the inspection and follow-up information, the Department issued a Notice of Violation, dated January 26, 2015, and revised on February 4, 2015, to VHC for the violations described in paragraph C(3), above.
- 5. On February 25, 2015, Department staff met with representatives of VHC to discuss the violations. At the meeting, VHC submitted a NOV response with supporting documentation, including the following:
 - a. A copy of the FA documentation that the DEQ Office of Financial Responsibility and Data Management had required no later than December 30, 2014. DEQ approved the revised FA mechanism on March 26, 2015.
 - b. Documentation of the procedures and education on the locking of RMW containers at all times, as well as keeping area clean of any RMW outside of container.
 - c. A signed quote for Shoemaker Construction to fix cracks and seams and seal entire hallway used for RMW storage.
 - d. Documentation stating that access to hallway has been restricted to essential waste management personnel utilizing card reader and magnetic lock. Staff instruction completed on not propping doors open. Security Department monitoring door 24/7.
 - e. Documentation stating that all carts are decontaminated utilizing Sani-master 4 liquid. Carts are cleaned by spraying carts down with

- decontaminate, power washing cart, and brushing carts cleaned. In addition, VHC is currently looking into purchasing an automatic cart washer.
- f. Records of STI Chem-clav temperatures from January 9, 2015 to February 12, 2015, all the test results from August, 2013 to February 2015, and the 2014 total RMW report for Virginia Hospital Center provided by Stericycle.
 - g. Documentation stating that VHC has reeducated all staff involved in maintaining the STI Chem-clav operations on the Facility's Infectious Waste Plan included DEQ reporting requirements.
 - h. Disclosure statement and list of key personnel.
6. On March 10, 2015, VHC submitted additional information to DEQ. The submission included the following:
- a. Revised procedure to conduct quality control of Chem-clav area was completed on March 6, 2015.
 - b. Construction of hallway concrete will be completed by April 1, 2015 (VHC has subsequently submitted a revised completion date of the end of July 2015).
 - c. On March 4, 2015, VHC installed labels outside of double doors at top of tunnel and outside door leading in that state "Infectious Waste Area, Authorized Access Only."
 - d. On March 6, 2015, added a cart cleaning procedure to the Chem-clav operator policy/procedure.
 - e. An updated "A test" procedure to include running the test with full load of trash, not as an empty load on March 6, 2015.
 - f. A Chem-clav temperature and process report for the machine. The chart included operating temperatures of the Chem-clav and the total process weight of the RMW treated by the unit.
 - g. Documentation of when the Chem-clav failed the "A tests" in November 2014 and December 2014 and where that specific failed load was shipped after the failed test.
 - h. Submitted a report for all the RMW processed during November 2014 – February 2015.
 - i. Scheduled training for spill kit and infectious waste handling for all employees who work in the basement (have to use the tunnel/hallway as an emergency egress). (The training was completed by June 9, 2015).
7. Based on the foregoing, the Board concludes that VHC as the owner and operator has violated: 9 VAC 20-70-111; 9 VAC 20-120-260; 9 VAC 20-120-340; 9 VAC 20-120-350; 9 VAC 20-120-380; 9 VAC 20-120-420, 9 VAC 20-120-640; and 9 VAC 20-120-760 as noted above.
8. VHC has submitted documentation that verifies that the violations described in paragraph C(3) above, have been corrected.

SECTION D: Agreement and Order

Accordingly, by virtue of the authority granted it in Va. Code § 10.1-1455(C) and (F), the Board orders Virginia Hospital Center, and Virginia Hospital Center, agrees to pay a civil charge of \$40,000.00 within 30 days of the effective date of the Order in settlement of the violations cited in this Order.

Payment shall be made by check, certified check, money order or cashier's check payable to the "Treasurer of Virginia," and delivered to:

Receipts Control
Department of Environmental Quality
Post Office Box 1104
Richmond, Virginia 23218

Virginia Hospital Center shall include their Federal Identification Numbers (FEINS) with the civil charge payment and shall indicate that the payment is being made in accordance with the requirements of this Order for deposit into the Virginia Environmental Emergency Response Fund (VEERF). If the Department has to refer collection of moneys due under this Order to the Department of Law, Virginia Hospital Center shall be liable for attorneys' fees of 30% of the amount outstanding.

SECTION E: Administrative Provisions

1. The Board may modify, rewrite, or amend this Order with the consent of Virginia Hospital Center for good cause shown by Virginia Hospital Center, or on its own motion pursuant to the Administrative Process Act, Va. Code § 2.2-4000 *et seq.*, after notice and opportunity to be heard.
2. This Order addresses and resolves only those violations specifically identified in Section C of this Order. This Order shall not preclude the Board or the Director from taking any action authorized by law, including but not limited to: (1) taking any action authorized by law regarding any additional, subsequent, or subsequently discovered violations; (2) seeking subsequent remediation of the facility; or (3) taking subsequent action to enforce the Order.
3. For purposes of this Order and subsequent actions with respect to this Order only, Virginia Hospital Center admits the jurisdictional allegations, findings of fact, and conclusions of law contained herein.
4. Virginia Hospital Center consents to venue in the Circuit Court of the City of Richmond for any civil action taken to enforce the terms of this Order.
5. Virginia Hospital Center declares they have received fair and due process under the Administrative Process Act and the Virginia Waste Management Act and it waives the right to any hearing or other administrative proceeding authorized or required by law or regulation,

and to any judicial review of any issue of fact or law contained herein. Nothing herein shall be construed as a waiver of the right to any administrative proceeding for, or to judicial review of, any action taken by the Board to modify, rewrite, amend, or enforce this Order.

6. Failure by Virginia Hospital Center to comply with any of the terms of this Order shall constitute a violation of an order of the Board. Nothing herein shall waive the initiation of appropriate enforcement actions or the issuance of additional orders as appropriate by the Board or the Director as a result of such violations. Nothing herein shall affect appropriate enforcement actions by any other federal, state, or local regulatory authority.
7. If any provision of this Order is found to be unenforceable for any reason, the remainder of the Order shall remain in full force and effect.
8. Virginia Hospital Center shall be responsible for failure to comply with any of the terms and conditions of this Order unless compliance is made impossible by earthquake, flood, other acts of God, war, strike, or such other unforeseeable circumstances beyond its control and not due to a lack of good faith or diligence on its part. Virginia Hospital Center shall demonstrate that such circumstances were beyond its control and not due to a lack of good faith or diligence on its part. Virginia Hospital Center shall notify the DEQ Regional Director verbally within 24 hours and in writing within three business days when circumstances are anticipated to occur, are occurring, or have occurred that may delay compliance or cause noncompliance with any requirement of the Order. Such notice shall set forth:
 - a. the reasons for the delay or noncompliance;
 - b. the projected duration of any such delay or noncompliance;
 - c. the measures taken and to be taken to prevent or minimize such delay or noncompliance; and
 - d. the timetable by which such measures will be implemented and the date full compliance will be achieved.

Failure to so notify the Regional Director verbally within 24 hours and in writing within three business days, of learning of any condition above, which the parties intend to assert will result in the impossibility of compliance, shall constitute a waiver of any claim to inability to comply with a requirement of this Order.

9. This Order is binding on the parties hereto and any successors in interest, designees and assigns, jointly and severally.
10. This Order shall become effective upon execution by both the Director or his designee and Virginia Hospital Center. Nevertheless, Virginia Hospital Center agrees to be bound by any compliance date which precedes the effective date of this Order.

11. This Order shall continue in effect until:

- a. The Director or his designee terminates the Order after Virginia Hospital Center has completed all of the requirements of the Order;
- b. Virginia Hospital Center petition the Director or his designee to terminate the Order after it has completed all of the requirements of the Order and the Director or his designee approves the termination of the Order; or
- c. the Director or Board terminates the Order in his or its sole discretion upon 30 days' written notice to Virginia Hospital Center.

Termination of this Order, or any obligation imposed in this Order, shall not operate to relieve Virginia Hospital Center from its obligation to comply with any statute, regulation, permit condition, other order, certificate, certification, standard, or requirement otherwise applicable.

12. Any plans, reports, schedules or specifications attached hereto or submitted by Virginia Hospital Center and approved by the Department pursuant to this Order are incorporated into this Order. Any non-compliance with such approved documents shall be considered a violation of this Order.
13. The undersigned representative of Virginia Hospital Center certifies that he or she is a responsible official authorized to enter into the terms and conditions of this Order and to execute and legally bind Virginia Hospital Center to this document. Any documents to be submitted pursuant to this Order shall also be submitted by a responsible official of Virginia Hospital Center.
14. This Order constitutes the entire agreement and understanding of the parties concerning settlement of the violations identified in Section C of this Order, and there are no representations, warranties, covenants, terms or conditions agreed upon between the parties other than those expressed in this Order.
15. By its signature below, Virginia Hospital Center voluntarily agrees to the issuance of this Order.

And it is so ORDERED this _____ day of _____, 2016.

Thomas A. Faha, NRO Regional Director
Department of Environmental Quality

Virginia Hospital Center voluntarily agrees to the issuance of this Order.

Date: 1/5/16 By: MIKE MALONE, VP, Admin. Services
(Person) (Title)
Virginia Hospital Center

Mike Malone

Commonwealth of Virginia
City/County of ARLINGTON

The foregoing document was signed and acknowledged before me this 5th day of

January, 2016, by Mike Malone who is

Vice President of Administrative Services of Virginia Hospital Center, on behalf of the corporation.

Tina C. Moshos
Notary Public

104817

Registration No.

My commission expires: 11-30-19

Notary seal:

Commonwealth Of Virginia
Tina C Moshos - Notary Public
Commission No. 104817
My Commission Expires 11/30/2019